K100520

NIPRO MEDICAL CORPORATION
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510(k) Summary for NIPRO BioHole Needle with CAPICK Scab Remover

807.92(a)(1)

Contact Person: Jessica Oswald
Regulatory Affairs Specialist

Date of summary preparation: February 22, 2010

MAR 17 2010

807.92(a)(2)

Trade Name: NIPRO BioHole Needle with CAPICK Scab Remover
Common Name: AVF Needle
Classification Name: Blood access Device and Accessories (21 CFR 876.5540)
Product Code: 78 FIE

807.92(a)(3)

Legally marketed substantial equivalent device:
NIPRO BioHole Needle: K060383
Medisystems ButtonHole Needle with SteriPick

807.92(a)(4)

Description of device:
The NIPRO BioHole Needle with CAPICK Scab Remover is a sterile, single-use device that consists of a hollow, winged needle, a flexible tube, mini clamp, locking connector and scab remover. This device is provided in four design types: fixed wing type A and B, and rotating wing type A and B. Needles are available in two lengths, 1" and 1¼", as well as four gauges (14-17), with and without back eye. The flexible tubing comes in lengths of 150mm and 300mm. The NIPRO BioHole Needle with CAPICK Scab Remover is packaged individually in a plastic pouch with paper backing, which contains labeling that adequately defines indications for use and warnings. Each BioHole Needle is provided with a sterile CAPICK scab remover attached to the cap of the needle. The CAPICK is intended to aid the clinician in the removal of the scab on the constant-site tunnel tract prior to cannulation with BioHole Needle.

These devices operate on the principles of a blood access device. They are sterile, single use only, non-toxic and non-pyrogenic.

807.92(a)(5)

Indications for Use:
The NIPRO BioHole Needle with CAPICK Scab Remover is intended for use as a blood access device for dialysis procedures using a constant-site cannulation technique of needle insertion with an established, mature constant-site also known as a buttonhole access site.

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807.92(a)(6)

Comparison of technological characteristics:
The NIPRO BioHole Needle with CAPICK Scab Remover is identical to the BioHole Needle in terms of indications for use, overall performance characteristics and materials of construction. It is also equivalent to the Medisystems ButtonHole Set with SteriPick in terms of labeling and instructions for use.

807.92(b)(1)

Non-clinical tests submitted:
Performance testing was conducted to verify that the device is safe and effective for its intended use. Those reports along with associated data are included in this submission.

807.92(b)(3)

Conclusions drawn from non-clinical and clinical tests:
The results of the performance testing and the comparison of technological characteristics demonstrate that the NIPRO BioHole Needle with CAPICK performs equivalent to the predicate device and is safe and effective when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G6
Silver Spring, MD 20993-0002

MAR 17 2010

Ms. Jessica Oswald
Regulatory Affairs Specialist
NIPRO Medical Corporation
3150 N.W. 107th Avenue
MIAMI FL 33172

Re: K100520
Trade/Device Name: NIPRO® BioHole Needle with CAPICK Scab Remover
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: FIE
Dated: February 22, 2010
Received: February 23, 2010

Dear Ms. Oswald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

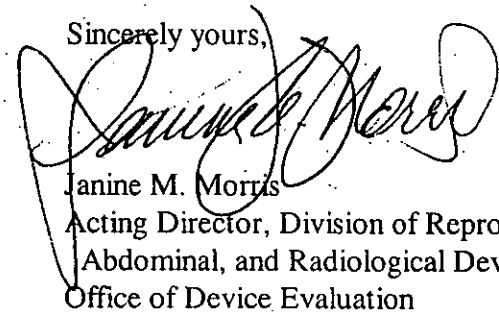
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Indications for Use

510(k) Number:

Device Name: NIPRO® BioHole Needle with CAPICK Scab Remover

Indications for Use:

The NIPRO BioHole Needle with CAPICK Scab Remover is intended for use as a blood access device for dialysis procedures using a constant-site cannulation technique of needle insertion with an established, mature constant-site also known as a buttonhole access site.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K100520